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CONTINUING CONCERNS WITH THE FEDERAL SELECT AGENT PROGRAM: DEPARTMENT OF DEFENSE SHIPMENTS OF LIVE ANTHRAX

TUESDAY, JULY 28, 2015

House of Representatives,

Subcommittee on Oversight and Investigations

Committee on Energy and Commerce

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:02 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Tim Murphy [Chairman of the Subcommittee] presiding.

Members present: Representatives Murphy, McKinley, Burgess, Blackburn, Griffith, Bucshon, Flores, Brooks, Mullin, Hudson, Collins, DeGette, Schakowsky, Castor, Tonko,

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Kennedy, Green, Welch, and Pallone (ex officio).

Staff present: Noelle Clemente, Press Secretary; Jessica Donlon, Counsel, Oversight and Investigations; Brittany Havens, Oversight Associate, Oversight and Investigations; Jessica Wilkerson, Oversight Associate, Oversight and Investigations; Christine Brennan, Democratic Press Secretary; Jeff Carroll, Democratic Staff Director; Ryan Gottschall, Democratic GAO Detailee; Chris Knauer, Democratic Oversight Staff Director; Una Lee, Democratic Chief Oversight Counsel; and Elizabeth Letter, Democratic Professional Staff Member.

Mr. {Murphy.} Good morning. Welcome to our hearing once again dealing with anthrax. The Subcommittee today examines continuing concerns over the Federal Select Agent Program. This time our focus is on shipments of live anthrax from a Department of Defense laboratory at the Dugway Proving Grounds that occurred over a nearly 10-year period. And as Yogi Berra said, it is like déjà vu all over again.

Last year, we held a similar hearing on a CDC anthrax incident that potentially exposed dozens of CDC researchers to live anthrax, due to the fact that established safety procedures were not followed. During the hearing CDC Director Frieden testified, ``We will take every step possible to prevent any future incident that could put our laboratory scientists and the public at risk.'' Yet here we are again today.

We also examined CDC's mistaken shipment of highly pathogenic avian flu and the FDA's discovery of vials of smallpox in an NIH building. Months after our hearing and after a White House-ordered safety stand-down and a laboratory sweep of all federal labs, the CDC revealed there

had been a transfer of Ebola from a CDC Level 4 lab to a CDC Level 2 lab. This is all deeply troubling. And despite the growing number of red flags, these incidents keep happening.

Now we have learned that the Dugway Proving Grounds, an Army lab in Utah, has inadvertently shipped live anthrax to facilities across the globe. At last count, at least 192 labs have received shipments of live anthrax. Apparently, Dugway's process to inactivate anthrax spores was not fully effective. And the sterility testing used to validate and ensure that the anthrax spores were inactivated failed to detect the live anthrax spores. What is most troubling, however, is that Dugway used this potentially deadly process for years.

As I said at last year's hearing, this is completely unacceptable. These dangerous safety lapses at our high-containment labs are threatening our Nation's security and public health. The Committee hopes to learn today what is being done this time to prevent future safety lapses. And will this be any different?

Last week, the Department of Defense released a report following its internal review of the circumstances

surrounding the live shipments of anthrax, and according to its report, the DoD was unable to definitively determine the root causes for how and why Dugway shipped live anthrax. Yet, in the report, the Department acknowledged that all its labs ``routinely operate outside validated experimental data for kill curves.''

So in other words, it seems that Department of Defense labs have been irradiating larger numbers of spores than recommended. And the labs should have known that they could not guarantee inactivation of all the anthrax spores at those numbers, especially at the dosage of radiation given.

This revelation begs a lot of questions, beginning with why? And why for so long? Who was responsible for making the decisions about which inactivation process to use, including how many spores and at what levels of radiation? Are these decisions evaluated and then ever re-evaluated? And what is the CDC's role in developing and evaluating these processes?

According to a recent and all-too-familiar headline, CDC has also announced that it will be conducting yet another comprehensive review of how it regulates safety and security

at bioterror labs. I think it is important to review current regulations to improve processes and procedures. But past reviews have not brought about the change necessary to truly improve safety and standardize processes and procedures. Maybe--we hope--this review will actually bring about different results.

As I said a year ago, what we have here is a pattern of recurring issues, of complacency, and a lax culture of safety. Last year, CDC Director Frieden stated that this was a wake-up call. However, it appears that critical government agencies have hit the snooze button once again. What is going to change things this time and when?

None of us want to be here again a year from now, discussing another set of safety lapses, and heaven forbid, a loss of life.

The U.S. Government Accountability Office has conducted comprehensive work on the oversight of high-containment labs. In fact, GAO has been issuing recommendations for years calling for a government-wide strategy for the requirements for high-containment labs and the need for national standards for designing, constructing, commissioning, and maintaining

such labs. Yet, these recommendations have not been implemented, which is one of the reasons we are here again today discussing another safety lapse that threatens national security and the public health.

Today I would like to thank our witnesses for testifying here. I look forward to hearing your testimony and learning from you. Please be candid and straightforward with us as we try to find ways to improve the safety and procedures in our bioterrorism labs. This Subcommittee will not relent in its oversight of Federal laboratories' compliance with select agent regulations, and will further explore the possibility of an independent agency to oversee these labs.

[The prepared statement of Mr. Murphy follows:]

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Mr. {Murphy.} I now recognize the Ranking Member Ms. DeGette of Colorado for 5 minutes.

Ms. {DeGette.} Thank you, Mr. Chairman. Mr. Chairman, you say you don't want to be back here in a year like we were last year, but we have been here in 2007, 2009, 2014, and now 2015. So might as well mark your calendar now. And part of that is because it is really important that the Federal Government work on identifying and containing public health risks. But the work itself inherently contains risk. And that is why we do have to continue our oversight.

At last year's hearing on the anthrax transfer I talked about the high-containment lab that we have in Fort Collins which some years ago we identified terrible lapses, and I was able to work with my former Republican colleague, Bob Schaffer, from that district to get a new lab built. I am proud of that work, but we have to continue to be able to assure our constituents that similar facilities across the country provide no risk to workers or to the broader community.

Now Mr. Chairman, as you said, frankly the details of

the Dugway incident do not inspire confidence. We are talking about a long-term series of inadvertent shipments of live anthrax from the Dugway Proving Ground in Utah which is supposedly one of the most sophisticated facilities in the world. This incident only came to light in May because a private company contacted CDC after discovering what it thought was inactivated anthrax was actually live anthrax.

Since then we have learned that 86 laboratories in 20 states and the District of Columbia and seven foreign countries received live anthrax spores from Dugway over the last 12 years. Those labs then transferred the live spores to an additional 106 labs. So we are talking about almost 200 labs in all 50 states accidentally receiving live anthrax for over a decade. Miraculously, nobody seems to have fallen ill as a result of this series of incidents. Still, like you, Mr. Chairman, I am concerned that this activity was going on for so long before one lab finally raised questions that spurred the Department to action.

I am eager to hear answers from DoD how this was allowed to happen in the first place and what they are doing to ensure it never happens again.

I understand that the Department's review of the Dugway incident released last week found there is insufficient scientific literature to develop effective protocols for the inactivation of anthrax spores. The Dugway lab was therefore relying on procedures that did not permanently or completely sterilize the anthrax spores.

Now, this is not my area of expertise, but it seems troubling on its face. How have we conducted research on this dangerous pathogen for the past decade without thoroughly understanding how to inactivate it? We need to conduct a serious examination of whether we use similarly questionable protocols for other select agents, and if so, I think we can all agree that we should immediately cease those operations to ensure we are not putting public health at risk.

For now, appropriately, DoD has issued a moratorium on shipping inactivated anthrax from its labs. This seems like an important first step, but I do want to know how that affects the research the lab was doing. Furthermore, I want clarification as how do we have 200 separate labs all across the country working with anthrax? Do we need to have 200

labs working with anthrax or is it possible that we could limit the number of labs and therefore limit the risk while still being able to do this important research?

I also want to hear today about whether the breakdowns at Dugway are indicative of broader problems at this site or even across the high-containment lab system. The labs that handle these pathogens must be held to the highest standards. Yet, the incidents that we have seen recently raise questions about whether we can trust high-containment labs to safely handle select agents.

Now in the last year, we have seen an anthrax exposure incident at CDC--this is what you said--improper shipments of avian flu, and even a potential Ebola exposure at a CDC lab. I feel really lucky that we haven't had anybody infected, but it could happen and I think we have just going on borrowed time here.

So I hope all of you have answers today about what we are really doing to make serious changes to the system and include recommendations that GAO has made.

I also want to hear from our witnesses about the role Congress should play in making sure the program operates

safely. And with that, Mr. Chairman, I yield back. Thank you.

[The prepared statement of Ms. DeGette follows:]

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Mr. {Murphy.} Thank you. Does anybody else on this side wish to make any opening statement or comments? If not, I would ask, and I don't know if you have seen this yet, Ms. DeGette and Mr. Pallone. The CDC article--an article appeared in last night's USA Today. I would like to have you look at it and see if you would have unanimous consent to submit that to the record. With no objection? This is titled CDC Lacked Key Lab Incident Reporting Policy Despite Scrutiny and Promises, and I think it is going to be relevant to today's hearing.

[The information follows:]

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Mr. {Murphy.} I now recognize Mr. Pallone for 5 minutes.

Mr. {Pallone.} Thank you, Mr. Chairman. I hope today we can get to the bottom of what happened at Dugway Proving Ground that resulted in live anthrax being shipped to 192 labs in all 50 states and at least seven foreign countries.

Deputy Defense Secretary Robert Work described these lapses as a ``massive institutional failure.'' I hope Dr. Hassell can explain to us today how these failures could possibly have occurred as well as what DoD is doing to strengthen and standardize safety protocols across all DoD labs as we move forward.

I am deeply relieved that no one has fallen ill as a result of these lapses, and I am hopeful that this will remain the case as DoD and CDC continue to track all the labs that receive these samples and the personnel that handle them. But this incident also raises broader questions about the safety of high-containment laboratories across the country.

Every day hundreds of labs in the Federal Government as

well as academic institutions and private companies handle dangerous pathogens and toxins under the Federal Select Agent Program. Make no mistake, these labs perform important work. High-containment labs play a critical role in biodefense by conducting research to improve our defenses against biological attacks and strengthening our public health response capabilities.

Laboratories that handle select agents are required to abide by a set of regulations commensurate with the risk that these agents pose. They are required to restrict access to select agents to individuals who have undergone a security risk assessment by the FBI and implements physical security safeguards, lab safety measure, and incident response plans. They must also ensure that laboratory workers are properly trained on biosafety and security measures.

Labs that participate in the program are also subject to registration and inspections by the CDC's Division of Select Agents and Toxins. There are civil penalties associated with lapses in safety protocols. Unauthorized possession or misuse of select agents is subject to severe criminal penalties. However, incidents in the past year involving

anthrax, Ebola, and highly pathogenic avian flu raise questions about whether we need to strengthen our federal oversight of labs that are working with dangerous pathogens. Is the current regulatory framework sufficient? Do the enforcement agencies have sufficient resources to ensure that oversight is robust? What is CDC doing to improve the Federal Select Agent program and prevent similar situations from occurring in the future?

I understand that CDC and DoD have conducted reviews of these incidents and have promised several more. I look forward to hearing about the findings and recommendations from those reviews and how they can be used to enhance safety and security at all of our Nation's high-containment laboratories. I also want to note that GAO has an important body of work that can inform this discussion. I look forward to hearing from GAO about its recommendations to strengthen safety measures across high-containment labs.

I am glad that nobody appears to have suffered any injuries because of this latest incident out of Dugway. The next time, however, the mishap may be from something more dangerous than liquid anthrax such as a highly infectious

pathogen. So I hope we can all learn from this latest incident and will take seriously the important recommendations made by recent and ongoing investigations by GAO and others to make this program safer. Obviously we look forward to a productive discussion today on how we can improve oversight and what this committee can do to facilitate that process and again thank our chairman and our ranking member as we proceed. I yield back.

[The prepared statement of Mr. Pallone follows:]

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Mr. {Murphy.} The gentleman yields back, and if no further comments from here, then we are going to go to our witnesses.

So as you are aware, when the committee is holding an investigative hearing, when doing so, has had the practice of taking testimony under oath. Do any of our witnesses today have any objections to testifying under oath? Seeing no objections, the chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel today? No. No one is asking for that.

In that case, would you please rise, raise your right hand, and I will swear you in?

[Witnesses sworn.]

Mr. {Murphy.} All of our witnesses have answered in the affirmative, and so now you are under oath and subject to the penalties set forth in Title 18, Section 1001, of the United States Code.

You may now each give a 5-minute summary of your written statement. Please pay attention to the lights there, and we

will start with you, Dr. Hassell, 5 minutes.

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^TESTIMONY OF D. CHRISTIAN HASSELL, DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL DEFENSE, DEPARTMENT OF DEFENSE; DAN SOSIN, DEPUTY DIRECTOR, OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION; GREGORY DEMSKE, CHIEF COUNSEL TO THE INSPECTOR GENERAL, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND MARCIA CROSSE, DIRECTOR, HEALTHCARE, GOVERNMENT ACCOUNTABILITY OFFICE

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^TESTIMONY OF D. CHRISTIAN HASSELL

} Mr. {Hassell.} Chairman Murphy, Ranking Member DeGette, and distinguished Members of the Subcommittee, I appreciate the opportunity to brief you today on the Department of Defense's inadvertent shipments of samples containing live Bacillus anthracis spores or anthrax. My name is David Hassell. I am the Deputy Assistant Secretary of Defense for Chemical and Biological Defense.

The Use of inactivated or dead anthrax is an important element of longstanding DoD programs to develop ways to

protect warfighters and the public from known biological threats, doing this with the development and testing of detection systems, protection equipment, diagnostics, and decontamination capabilities.

We first learned of the incidents under consideration today on May 22 of 2015 when the Centers for Disease Control and Prevention was alerted by a private company regarding the growth of live anthrax in a sample that was inactivated by a laboratory at the Army's Dugway Proving Ground in Utah. The CDC immediately began an investigation, working with DoD laboratories, state officials, and the FBI.

By May 25, all known laboratories that received inactivated anthrax samples from that same batch had been notified and instructed to stop working with the samples. Also on May 25th the four DoD laboratories that produce inactivated anthrax were directed to stop producing, shipping, and working with any inactivated anthrax other than for purposes related to this current matter.

Subsequent tests by Dugway identified other batches of inactivated anthrax as containing live spores, and on June 2nd the Department of Defense notified all known recipients of

inactivated anthrax from Dugway to stop working with the material, whether it was confirmed to contain live anthrax or not.

There's no known or suspected cases of anthrax infection among workers at any of the laboratories that produced or received inactivated anthrax, and there is no known risk to the general health and very little risk to laboratory workers themselves. However, as a precaution, 31 U.S. citizens, 8 non-DoD, 23 DoD, were placed on post-exposure prophylaxis treatment, and this was completed yesterday.

Returning to the subject of the four DoD Laboratories that produce inactivated anthrax, on May 29th the Deputy Secretary directed that those four DoD laboratories test all previously inactivated anthrax that was in their inventory to identify the presence of any live spores. That testing is now complete, and the results are as follows: Since 2003, the four DoD laboratories irradiated a total of 149 batches of live anthrax spores. Of the 96 samples that were available to test, 17 tested positive for the presence of live anthrax. All of these originated from Dugway.

We now know that over the past 12 years, 86 laboratories in 20 states, D.C., and seven foreign countries received directly from Dugway inactivated samples that contained live spores. In addition, the CDC has informed us that an additional 106 labs received secondary transfers from some of the original 86 direct recipient labs. This brings the total to 192 labs in all 50 States, D.C., and three Territories of Guam, Puerto Rico, the U.S. Virgin Islands.

A recently completed Comprehensive Review of the root causes of the incident resulted in several key findings including that the primary systemic issue is the lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures, and the resulting recommendations are grouped into three broad categories being enhance quality control programs, establish testing protocols that are based on relevant scientific data, and improve program management.

The Department is committed to ensuring that this doesn't occur again and will implement the recommendations that were in the report and the further directives outlined by Deputy Secretary Work on 23rd of July. In the interim, the

aforementioned moratorium will continue. Our top priority is the safety of all involved, and we remain committed to complete transparency of information as we go forward. Thank you for the opportunity to testify today, and I'll welcome your questions.

[The prepared statement of Mr. Hassell follows:]

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Mr. {Murphy.} Thank you, Dr. Hassell. Dr. Sosin, before you speak, I just want to note that we haven't really had the chance to review a lot of your testimony because it wasn't in until 9:00 last night, and the committee rules, we ask for 48 hours. So we really didn't have time to review that. So when we get the testimony at the last minute, it is difficult for us to review it. I don't want to think that CDC is trying to frustrate our purposes here, but I do want to indicate to you and if you could pass the word onto CDC department that for future testimony, we want that 48-hour limit adhered to.

So at this point, we would like to hear from you for 5 minutes. Thank you.

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^TESTIMONY OF DAN SOSIN

} Mr. {Sosin.} Thank you. Chairman Murphy, Ranking Member DeGette, distinguished members of the subcommittee, I want to thank you for this opportunity to testify before you today. I would like to share with you what CDC has done to respond to the inadvertent release of live Bacillus anthracis spores, or anthrax, from Dugway Proving Ground and to provide perspective on the Select Agent Program that CDC supports.

CDC works 24/7 to save lives and protect people. We activated our emergency operation center in face of uncertainty about the scope and severity of this release. We understand how concerning this incident has been, and our primary focus continues to be making certain people are safe and that anthrax materials are secured and ultimately disposed of.

This incident raises serious and challenging issues. It is important to note, however, that scientific research in laboratories is a vital component of our Nation's defense against naturally occurring diseases and bioterrorism. This

research is complex and sometimes dangerous. While it is not possible to eliminate all risk, those of us working in this field across the country and around the world must do all we can to minimize risk.

Here's what we know about today about the Dugway incident. There have been no suspected or confirmed cases of anthrax infection associated with these samples. Persons that CDC has assessed is at some risk and who have accepted treatment will have completed antibiotic and vaccine prophylaxis yesterday, and no complications have been reported.

The facilities that received these samples have appropriately secured or destroyed them, and those needing decontamination have completed the procedures or are well under way.

Highlighting this positive news is not meant to downplay the seriousness of the situation. On multiple occasions over more than a decade the production methods at Dugway failed to inactive anthrax spores. The failure of inactivation was evident because growth was being detected on multiple production runs. These runs were routinely sent back for

additional irradiation. This should have been seen for what it was, an indication that the margin of safety with the method was not sufficient. Additionally, sterility testing at Dugway to confirm the inactivation was successful at killing the organism failed to detect live spores.

We have looked and found no evidence of a similar problem at other facilities that inactivate anthrax spores. The existing rules and regulations on anthrax spore inactivation are under review.

Here's what we don't know. The Federal Select Agent Program relies primarily on sterility testing to assure that a select agent can no longer grow. We remain unsure whether there was a problem with the execution of this testing at Dugway or if the biology of spores was not sufficiently understood to make the procedure reliable.

And here's what we are doing moving forward. We are maintaining a moratorium on the use and transfer of inactivated anthrax spores until we have an acceptable and credible approach to increasing safety and security. And we are developing a research agenda on spore biology to answer

questions about inactivation and sterility, and we will help to conduct some of that research.

At Dr. Frieden's direction, we are initiating a review of the CDC Federal Select Agent Program. The review will complement ongoing work to improve laboratory safety at CDC this past year. The time is right with new leadership over the CDC Federal Select Agent Program for a thorough review of our program to ensure it's meeting its mandate, especially in light of recent lab incidents.

The world benefits from discoveries made working with dangerous pathogens, and the scientists who work with these organisms also have a commitment to protecting public health and safety. We must achieve a balance to protect workers and the communities around them while encouraging and supporting scientific advancement. But safety comes first.

One characteristic of CDC's stewardship of the Federal Select Agent Program is a commitment to improvement. The regulations have been refined with advice from many including numerous federal advisory and review bodies and the public. This input has led to revisions to the select agent regulations concerning personnel reliability, incident

reporting, coordination of inspections with federal partners, and tracking shipments of select agents.

Although much work has been done to enhance the effectiveness of CDC's regulatory oversight of select agents and toxins, more work remains to be done. Where improvements can be made to better the program, we will make them. Whether there is disagreement on the best path forward, we will contribute our scientific and programmatic expertise to the debate. We will work diligently and thoughtfully with anyone sharing our commitment to protect Americans from biological threats. Thank you.

[The prepared statement of Mr. Sosin follows:]

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Mr. {Murphy.} Thank you. Dr. Demske, you are recognized for 5 minutes.

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^TESTIMONY OF GREGORY DEMSKE

} Mr. {Demske.} Good morning, Chairman Murphy, Ranking Member DeGette, members of the subcommittee, I'm Greg Demske, Chief Counsel to the Inspector General at the Department of Health and Human Services. I appreciate the opportunity to appear before you today to discuss the Federal Select Agent Program.

While CDC administers the Select Agent Program with the Department of Agriculture, OIG is authorized to impose civil money penalties for violations of the regulations. We also audit, evaluate, and offer suggestions for program improvement. CDC reviews all potential select agent violations and immediately refers urgent or criminal matters to the FBI. In other matters, CDC further investigates and determines whether to exercise its authority to suspend or revoke registration or require remedial actions. If CDC concludes a civil violation may have occurred, it refers the case for OIG for potential enforcement.

OIG carefully evaluates every referral and decides

whether to pursue the case and what penalty to seek based on the facts and circumstances of the particular case. In our experience, violations of the regulations pose varying risks to public health and safety. To date, OIG has imposed 20 CMPs totaling $2.4 million for select agent violations. Two of our cases have involved Dugway.

In April 2007, Dugway shipped anthrax to a research facility. The shipment included a certification that the anthrax was non-viable. The research facility tested the material and found the presence of a low concentration of viable anthrax. We found that Dugway ignored the results of its post-inactivation viability test which showed viable anthrax was present. Later, in November 2010, a government laboratory received a shipment from Dugway that included a vial of Botulinum neurotoxin. Small amounts of this select agent are exempt from the regulations. The packing slip indicated that the vial contained an exempt amount, but in fact, the shipment included a regulated amount. Dugway then self-reported two other unauthorized shipments of this select agent.

As a federal entity, Dugway presents an enforcement

challenge for OIG. Any CMP on a federal entity would simply shift money within the government at a net cost to taxpayers and may not promote better compliance. Consistent with our approach to date with other federal entities, OIG issued Notice of Violation letters to Dugway for both cases. Both letters stated that OIG had determined Dugway had violated the select agent regulations and it should examine its current policies and practices, take corrective action, and monitor its safeguards on an ongoing basis. Yesterday OIG received another referral from CDC on Dugway. We are reviewing the matter now.

Over the years OIG has audited government and private entities for select agent compliance. For example, OIG audited six federal laboratories and provided audit results to the heads of the relevant federal agencies, putting them on notice of deficiencies. OIG is expanding our audits and evaluations of select agent management. We will focus on CDC's oversight of the Select Agent Program and on the operation of HHS laboratories that handle select agents.

Through our enforcement work, OIG has also identified several opportunities to improve program compliance,

oversight, and enforcement. As reflected in my written testimony, these opportunities focus on enhanced documentation requirements and increased authority for CDC inspectors. We stand ready to work with CDC and others in HHS to continue to improve the Select Agent Program and use our enforcement tools to promote compliance with these regulations that protect the health and safety of the American people.

Thank you again for inviting me to speak. I'd be happy to answer questions.

[The prepared statement of Mr. Demske follows:]

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Mr. {Murphy.} Thank you, Mr. Demske. Dr. Crosse, you are recognized for 5 minutes.

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^TESTIMONY OF MARCIA CROSSE

} Ms. {Crosse.} Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, I'm pleased to be here today to discuss GAO's work on high-containment laboratories. The biosafety and biosecurity practices in these laboratories are intended to reduce the exposure to biological agents and prevent their loss, theft, or misuse.

The recent shipments of live anthrax bacteria from DoD to U.S. and international laboratories, similar to last year's potential exposures of CDC personnel to live anthrax bacteria, shows multiple breakdowns in compliance with established policies and inadequate oversight of federal high-containment laboratories. This is another example in an ongoing series of safety lapses which continue to occur, often with the same root cause as for prior incidents.

We've been lucky so far. Researchers in these labs work with high-risk biological agents that may result in serious or lethal infections and, in some instances, have the potential to be used in biological weapons. These labs do

important work with pathogens to develop vaccines and countermeasures and to understand emerging infectious diseases. However, the pathogens handled by these laboratories also have the potential for high-consequence accidents. If the types of mistakes we've seen were to occur with a particularly transmissible pathogen like certain strains of influenza, not only would the laboratory workers or their close contacts be at risk but an epidemic could be triggered with consequences far beyond what we've seen to date.

GAO is currently conducting work for this committee to examine these issues, and the preliminary findings from our work show that DoD and CDC have begun to address weaknesses in the management of their high-containment laboratories but have not yet fully implemented these activities. The steps these agencies are taking are intended to address fundamental flaws in the oversight structure, reporting, and tracking of biosafety and biosecurity incidents after they have occurred. For example, DoD officials said that the Dugway incident is the first incident that DoD has tracked at the senior department level. Since 2012 DoD has been revising its

policies and procedures including reporting requirements and expects to finalize these changes by this fall. But these changes will only cover a subset of DoD's high-containment laboratories.

Our ongoing work will also examine if DoD is implementing steps intended to improve the culture of safety at its laboratories so that future events are reduced or prevented.

Similarly, CDC began taking steps to address weaknesses identified in assessments of the June 2014 anthrax incident and other safety incidents in its own laboratories, but the agency has not yet completed implementing recommendations intended to improve its laboratory oversight. For example, an internal work group recommended that CDC develop agency-wide policies to provide clear and consistent requirements for biosafety for all agency laboratories. In response, CDC developed a Specimen Transport Policy but has not developed other agency-wide policies, such as requirements for laboratory documentation and emergency protocols.

As I stated at the outset, the incidents you are examining today are part of a long series of safety lapses.

Since 2007, GAO has reported on these issues and has made multiple recommendations to improve federal oversight of high-containment laboratories. The federal departments agreed with our recommendations and have conducted some activities to respond but have not implemented our key recommendation to establish a single federal entity with responsibility for oversight of all high-containment laboratories.

We recommended the establishment of a single federal entity to, one, conduct government-wide strategic planning for requirements for high-containment laboratories, including assessments of their risks; and two, develop national standards for designing, constructing, commissioning, operating, and maintaining such laboratories.

We continue to believe that such an entity or some other mechanism to ensure higher level oversight is needed in the face of the continuing proliferation of high-containment laboratories and the ongoing failures by agencies to fix their problems on their own.

In closing, the lapses we've seen are indicative of failures in a system that is supposed to have multiple levels

of control, including cross-checks, inspections, training, procedures, and validated protocols that should prevent such accidents from occurring and certainly should prevent such incidents from recurring.

Mr. Chairman, this completes my remarks. I'd be happy to answer questions you or other members of the subcommittee may have.

[The prepared statement of Ms. Crosse follows:]

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Mr. {Murphy.} Thank you, Doctor. I will now recognize myself for 5 minutes of questioning of the witnesses. Dr. Sosin, at the end of your testimony you said we will work diligently and thoughtfully with all of our federal partners and anyone sharing our commitment to protect Americans from biological threats. Please let the CDC know, I don't believe them anymore.

The USA Today article I referenced earlier said that the CDC refused to actually produce a policy to USA Today regarding the lab incident reports in this newly required lab safety office. When was that report actually written? Do you have any idea?

Mr. {Sosin.} Thank you, Chairman. I was asked to appear here today, and I apologize for the lateness of testimony. I apologize that--

Mr. {Murphy.} But do you know anything about this report that they are referring to in USA Today?

Mr. {Sosin.} I know that an article came out last night. I did not know about that report and--

Mr. {Murphy.} Okay.

Mr. {Sosin.} --and if--

Mr. {Murphy.} Well, could you--

Mr. {Sosin.} We would be happy to assure that after this hearing we provide you answers to--

Mr. {Murphy.} Well, this committee would like that report. I would like to know when it was written. If we could have that, that would be valuable. Thank you.

Dr. Hassell, I am trying to dumb this down. Now if I put a cup of coffee in a microwave oven and turn it on, it gets hot in a certain amount of time. If I put a dozen cups of coffee in that same microwave, same amount of time, they are not going to all be heated, right? Okay. Because we know that about radiation and mass, some physics principles.

[Slide.]

When I look here, and I believe this is from a report here and it is on the graph there as well is that--on the screen--that on the very upper left dot where it says the Dugway irradiation levels here, it is saying it is operating way out of the realm of the acceptable processes here. And the report states that the DoD routinely operates outside of validated experimental data for kill curves.

So based upon that finding, it sounds like validated experimental data does exist in all the DoD labs whose mission involved inactivation of anthrax were operating outside of it. Is that correct?

Mr. {Hassell.} Yes, sir.

Mr. {Murphy.} So is there--who is responsible for setting the number of spores and dosage of radiation? And are the protocols reevaluated routinely to determine that?

Mr. {Hassell.} That is one of the next steps we are looking into. This original review was mainly focused on compliance to make sure that people were following the protocols they had and not show there was the willful disregard for the protocols or nefarious intent.

Mr. {Murphy.} You said it was willful?

Mr. {Hassell.} It was not willful nor was it nefarious. But what the graph shows, though, is they were working outside of that gray box that sort of shows experimental parameters that should have been the foundation for this work.

The next step in this is we are looking at the very accountability issue. How was that decision made to move

outside of that realm? And as you noted, it wasn't just Dugway. All the labs were outside of that area.

Mr. {Murphy.} Because somebody did make the decision. That is something that is important. We need to know because we like to think that there is a scientific rule set up that they are following and that all the labs are following that, too. So let me ask Dr. Hassell and Dr. Sosin, in response to these most recent shipments of live anthrax, have either of your agencies made any personnel changes or refer to anyone for their civil penalties or criminal prosecutions for these actions? Have either one of your agencies done that?

Mr. {Hassell.} So like first answer, for DoD, that is that second part of the investigation that will kick off now looking the accountability issue to determine that. And if I may, one of the issues is not only the individual that made that decision, if that was an individual that made that decision, but what was the process? Was there an overall systemic process that led people to perhaps gradually get outside of that experimental box? We are looking at both of those, but the accountability is taken very seriously by all seniors in the Department.

Mr. {Murphy.} Dr. Sosin?

Mr. {Sosin.} I would also like to acknowledge that we understand your concern and take it seriously. No disciplinary actions have been taken at CDC with respect to the DoD sample incident. In fact, CDC staff responded in a remarkable way to assure that all these samples were secured and destroyed and that the people that might have been exposed were protected.

Regarding the Select Agent Program, we continue to consider and take advice and input on how to change the nature of the program--

Mr. {Murphy.} Do you work with the DoD? I mean, does the CDC work with other labs in terms of setting and reviewing standards on any regular basis or at all?

Mr. {Sosin.} CDC works with DoD in a variety of ways.

Mr. {Murphy.} With regard to this? So I am trying to find out--

Mr. {Sosin.} Not with respect to setting standards--

Mr. {Murphy.} Okay.

Mr. {Sosin.} --on anthrax.

Mr. {Murphy.} And the reason is this. When we had our

hearings for General Motors and someone made the decision of either making a spring this big or this big, and it cost a number of lives. And they refer to that as the GM shrug. People said, eh. Well, some engineer decided, on we go. And it is that area when we know when people adhere to scientific standards, I have the highest respect for them. When things begin to slip out--and I would agree. We are not looking at something nefarious or deliberate here, but it to let anything slip by over time that is the problem. And as Mr. Pallone pointed out, luckily no one has died yet from this, but we really have dodged the bullet for a long time.

But I see I am out of time. I recognize Ms. DeGette for 5 minutes.

Ms. {DeGette.} Now Dr. Crosse, you talked in your testimony about how people could be infected and even some kind of epidemic could be started if you got a particularly virulent agent that got released, correct?

Ms. {Crosse.} Correct.

Ms. {DeGette.} In addition, we have got national security implications relating to the mishandling of these agents. Is that also correct?

Ms. {Crosse.} That is also a concern.

Ms. {DeGette.} And that is if these agents, these active agents got into the wrong hands, right?

Ms. {Crosse.} That is right.

Ms. {DeGette.} Now, you had a lot of recommendations that have not been fully implemented yet, is that right?

Ms. {Crosse.} Yes, although--I mean, many of the recommendations they have taken at least some actions. The primary one where there has been no movement is to have some type of more centralized oversight.

Ms. {DeGette.} So to have a single federal entity that could set the standards for all of the agencies, is that right?

Ms. {Crosse.} That is right.

Ms. {DeGette.} Now Dr. Hassell, what is your agency's opinion about that recommendation of a single federal entity?

Mr. {Hassell.} It makes sense in many ways. I will say that within the Department itself, we are going to do that internally because it is so--

Ms. {DeGette.} Okay. So if it makes sense in many ways, why haven't we done that? Why haven't you guys

implemented that in cooperation with your fellow agencies?

Mr. {Hassell.} Like I say, we are going to do that internally. We are in discussions now on these issues.

Ms. {DeGette.} But you don't disagree with the idea?

Mr. {Hassell.} No, ma'am.

Ms. {DeGette.} And what about you, Dr. Sosin? What is your agency's view of this?

Mr. {Sosin.} CDC works with APHIS at USDA as if we are one program. We work very closely. We do joint inspections on overlap agents. Whenever a change is proposed or considered in one program, it is discussed with the other program.

Ms. {DeGette.} Well, that is nice, but what about DoD?

Mr. {Sosin.} So the oversight function of the lab--I am trying to understand your question. I believe--

Ms. {DeGette.} Well, okay.

Mr. {Sosin.} --it is about oversight function, correct?

Ms. {DeGette.} What Dr. Crosse's agency is recommending is one single oversight agency that would set forth the protocols for the dispensing of these agents. And so I am asking each of your agencies if you would object to that kind

of--it would make sense to me to get one protocol no matter which lab is dispensing it or whatever. What is your view on that?

Mr. {Sosin.} Thank you. My view is that it is a complex decision, that there are constraints to having one standard for all procedures. Anthrax for example--

Ms. {DeGette.} What constraints would those be?

Mr. {Sosin.} For example with anthrax, there are many different uses of the products, DNA preps for developing vaccines--

Ms. {DeGette.} But in any case if you are sending it around, you don't want it to be live.

Mr. {Sosin.} That is absolutely--

Ms. {DeGette.} That is not something that is--

Mr. {Sosin.} No question.

Ms. {DeGette.} --subject to debate. So if you can have one agency that could come up with the protocols about oversight on how you are going to make that not be live and how you are going to dispense it, you wouldn't object to that, would you?

Mr. {Sosin.} We wouldn't object, and we believe that

the Select Agent Program, the Federal Select Agent Program, would be the appropriate body to do that. It will take--

Ms. {DeGette.} Okay. Could that have oversight over the DoD, too?

Mr. {Sosin.} Absolutely.

Ms. {DeGette.} So do you think that you might cooperate to make that happen?

Mr. {Sosin.} We will cooperate in any way to--

Ms. {DeGette.} Okay. Let us know what we can do to help you because it seems to me that is an excellent recommendation, okay? And you are nodding, Dr. Hassell. Can you work with Dr. Sosin on that and his other colleagues?

Mr. {Hassell.} Yes, ma'am, and that was--

Ms. {DeGette.} Thank you.

Mr. {Hassell.} --stated in the statement. We definitely are--we are working together.

Ms. {DeGette.} Okay. Now here is something else, having been on this committee for a long time. I have noticed this at all the federal labs, not just the ones dealing with anthrax and other select agents but also our nuclear labs have the same problem of a culture of safety,

and we have really struggled in this committee to get people to understand how important it is to have a culture of safety. So Dr. Hassell, can you think of anything we can do to systematize some kind of culture of safety?

Mr. {Hassell.} That is a question I have myself, ma'am. I have spent 10 years at the DuPont Company which goes back 200 years making gunpowder for Thomas Jefferson. And that safety culture is there. So one of the things I plan to do is go out and see those industry best practices for doing this that the government--

Ms. {DeGette.} How long--

Ms. {Hassell.} --perhaps could adopt.

Ms. {DeGette.} How long have you been there?

Mr. {Hassell.} At the--

Ms. {DeGette.} At DoD.

Mr. {Hassell.} Just about a year today.

Ms. {DeGette.} Okay. And Dr. Sosin, do you have some ideas about how we can increase the culture of safety at these labs?

Mr. {Sosin.} I personally do not. I know that the CDC and CDC's Director takes this issue incredibly seriously and

has developed a series of ideas that will evolve.

Ms. {DeGette.} Okay. I think we need you guys to supplement your testimony about this because this is really important. And I have one other question. I don't have time, but I would like a written answer for this. I would like to know why all of the problems in this particular incident seem to have come out of this one lab. Was it a problem with how they were handling this anthrax, how they were trying to treat it or is it a problem with the procedure itself? And maybe that is what you are investigating right now, but that seems like the crux of the problem.

Thank you, Mr. Chairman.

Mr. {Murphy.} The gentlelady's time has expired. I will now recognize the vice chairman of the subcommittee, Mr. McKinley, for 5 minutes.

Mr. {McKinley.} Thank you, Mr. Chairman. This is a subject I acknowledge is foreign to me. So I was delighted to try to hear and learn from some of your testimony on this. But I am just curious before I have got a list of six questions. I am trying to go back to the fundamentals. Why would we ship inactive cells to laboratories? What would you

gain by shipping something that is dead?

Mr. {Hassell.} Maybe we could--

Mr. {McKinley.} You have to use the microphone.

Mr. {Hassell.} So one of the aspects of this inactivated anthrax is that it maintains the shell that is around the original live spore. The physical structure is still there. That is important because that is the basis for the detection systems and the diagnostic systems that are developed.

Mr. {McKinley.} Okay. That--

Mr. {Hassell.} So the closer we can get to that the better we are.

Mr. {McKinley.} That helps a little bit to explain. Let's go back to something that the gentlelady from Colorado mentioned earlier that I didn't pick in the reading. We are doing this in 200 laboratories around the country? Is that an accurate statement? We are studying that in 200 laboratories? We have live anthrax in 200 laboratories?

Mr. {Sosin.} The statement there though are 192 labs that receive this material were not intended to receive live anthrax. There are 181 registered entities within the

Federal Select Agent Program registered to possess, use, or transfer Bacillus anthracis.

Mr. {McKinley.} Okay. So apparently there is some--I would struggle with that to understand why we have to have 300 or 200 looking at some of--I would really, especially given the circumstances of this. Dr. Crosse, before I get to--again, I am going to run out of time here I think--how would you grade the DoD's handling of this matter? Would you give them an A on how they handled it? An F? Give me a--

Ms. {Crosse.} Well, since the incident was reported, they have moved pretty quickly to identify where the samples were sent, although that was still developing over the last few days and they have--

Mr. {McKinley.} How would you grade it? Would you grade it passing? Acceptable? A B? A C?

Ms. {Crosse.} I think their response, once it was discovered, has probably been a B. I think the activities leading up to it and the fact that this went on for so long is definitely a failure.

Mr. {McKinley.} Well, I understand it has been going on for 10 years?

Ms. {Crosse.} Yes. That is a failure and that fact that they have four different laboratories inactivating anthrax with four different methods and with four different chains of command that don't talk to one another.

Mr. {McKinley.} Go back to Dr. Hassell. Since anthrax is probably the most dangerous agent that we can handle, I suppose it is more dangerous than Ebola. But getting it, getting that, is probably the biggest threat that we have in national security that someone doesn't get this agent. So in this case, has anyone tried to grow this live anthrax after they have received these products, with 200 laboratories? Have they tried to reactivate it?

Mr. {Hassell.} It was grown to show the presence of the live spores. I may not be understanding your question. I apologize.

Mr. {McKinley.} Okay. Well, let me move on because I only have 1 minute left. And so is this the same type of anthrax that was used in 2001?

Mr. {Sosin.} This is absolutely not the same type of anthrax used in 2001. This is a wild type anthrax. It was in a liquid formulation with extremely small numbers of

spores in a 1 Ml sample. Very different situation, nonetheless, taken extremely serious.

Mr. {McKinley.} So this is something that different--do you feel that our national security is more at risk because of the process we have been handling this for the last 10 years?

Mr. {Sosin.} The CDC--

Mr. {McKinley.} It is a yes or a no, isn't it?

Mr. {Sosin.} I don't believe that these samples created such a risk. I believe that they were secured quickly and destroyed, that there are very small numbers of spores in this material and that it is naturally occurring type of anthrax.

Mr. {McKinley.} Let me ask in the last--well, my thought process initially--why we were shipping this to seven foreign nations? Does someone have a written authorization? Is there one of those proverbial emails that someone was requesting this? And then who authorizes the shipment of that and under what process do they explain how they want to get it? Why would we ship to seven foreign nations?

Mr. {Hassell.} So in several cases, those were actually

DoD facilities that were located in those foreign nations, and other cases they were allies that--

Mr. {McKinley.} We don't have enough DoD facilities in America that we have to go overseas? I am running out of time.

Mr. {Murphy.} Okay. I now recognize Mr. Green for 5 minutes.

Mr. {Green.} Thank you, Mr. Chairman. Unfortunately, the incident that led to today's hearing is not the first instance of issues of handling and shipment of bioagents at Dugway Proving Grounds. CDC and the Office of Inspector General examined safety lapses at Dugway in 2007. The result? The same kinds of problems we are hearing about today, failing to properly inactivate anthrax specimens. Is that correct, Dr. Hassell?

Mr. {Hassell.} Yes, sir.

Mr. {Green.} Based on the previous problem, should Dugway have made a better effort to check its procedures and double-check the samples to see if the process worked?

Mr. {Hassell.} That is my initial impression. We are going to be looking at that much more because there were some

serious implications there, and we are going to be following up on that much more. So we can report back.

Mr. {Green.} Similarly when the CDC announced last year that it had inadvertently transferred live anthrax, did DoD as a precautionary measure direct its lab to check their own processes for ensuring that anthrax was inactivated properly?

Mr. {Hassell.} No, sir.

Mr. {Green.} Why not?

Mr. {Hassell.} I am not sure. That is a good question. We are going back and trying to figure out what were the steps leading up to this. It should have been better indicators that we could have taken action and detected this earlier.

Mr. {Green.} Well, again, I think the reason for the hearing is it seems kind of strange that, you know, CDC made a mistake and we had a problem with a DoD facility, and somebody in management authority didn't say let's check to make sure the DoD is doing it right because of what happened at the CDC, particularly because of the problem at Dugway. Nobody decided to do that?

Mr. {Hassell.} It doesn't appear so, sir.

Mr. {Green.} Beyond the particulars of this anthrax incident, it is a fact that such shipments of live anthrax can accidentally occur raises serious questions about the handling of select agents at both Dugway and other DoD labs.

Dr. Hassell, based on the continuing problems we did find at Dugway, what assurance can you give the subcommittee that there is no long-standing safety problems at Dugway or at other DoD facilities that handle high-risk biological agents?

Mr. {Hassell.} So that is a good question. We are trying to look and see if there are some general lessons we can learn from this and use it to ask some of the questions such as your previous question. Just internally, are there indicators here that would indicate we need to be asking other questions about other operations across the whole complex.

Mr. {Green.} What is DoD doing to look across all of its facilities and check their biosafety and biosecurity policies and procedure are adequate?

Mr. {Hassell.} We are undertaking an effort now to look at that, as was pointed out earlier, the chain of command is

disparate right now. So we are trying to tighten that up. We are going to make sure that the standards for example for the inactivated anthrax, we will ensure internally that that's standardized across all the laboratories. And then we can use that as the basis and see if there are other operations that we need to take some more actions on.

All four of those facilities do different activities. Dugway is largely a production facility. The other ones are more research facilities. So one size may not fit all, but there are definite lessons we could learn from this, and whenever possible, we will standardize.

Mr. {Green.} How is DoD ensuring a serious issue such as potential exposures or concerns about misuse are communicated from the laboratories to the senior leadership?

Mr. {Hassell.} Some of the recommendations have been made previously we are going to be more vigorous on. The DoD instruction that was mentioned earlier that has been in process, that will include aspects that will bring all of the reporting forward to a higher level. So for example, the 2007 incident, that will not just remain--if that had happened today, that wouldn't just remain at Dugway or that

immediate command. It would come all the way up to a central office within the Department. We would review all of those. We're in the process now of pulling in all of the Inspector General reports, CDC reports from all of the laboratories up to my office, and we're reviewing all of those to see if there are indicators and lessons to be learned.

Mr. {Green.} Well, following my colleague from West Virginia, so far we have been extremely fortunate these incidents at Dugway have not led to broader public health or security problems, and I hope today's hearing and other ongoing oversight of this incident serves as a call to action to tighten up these processes, not just for anthrax and at Dugway but other select agents and at all facilities. We don't want to have to have somebody here again or I hope the Armed Services Committee is also looking at it and seeing that the issues are being corrected.

Mr. Chairman, I yield back my time.

Mr. {Murphy.} The gentleman yields back. I now recognize Dr. Burgess for 5 minutes.

Mr. {Burgess.} Thank you, Mr. Chairman. Thanks to our witnesses for being here today.

Dr. Sosin, let me just ask you a couple of questions basically about what we are doing to harden our public health infrastructure in locations where these agents may be under study because we have heard sort of a recurrent theme. I certainly appreciate what Ranking Member DeGette has said earlier. I mean, I have been on this committee for a number of years as well, and it seems like there is a recurrent theme here. We want everything to be perfect, but there are human beings involved and sometimes they aren't perfect. So I remember reading--I was just a regular guy in private practice when the anthrax attack happened in 2001. I remember reading with just absolute horror what happened when those five individuals were infected and subsequently died, reading about their emergency room doctor's experience that here was a guy that didn't look that sick. He looked like the last 700 people that just walked in the door, but as we found out with anthrax, you can be a lot sicker than what you look. And by the time clinical deterioration begins, you are almost too late on the curve to rescue someone, although rescue is possible if you start early. Because unlike Ebola, anthrax is treatable with relatively common antibiotics.

So bearing in mind that Ebola experience from not quite a year ago, CDC was telling us last July, August, September, we got everybody up to speed about Ebola. We don't have to worry about Ebola coming to this country. The President made a statement that we don't have to worry about Ebola coming to this country. The CDC has done what it needs to do to get everybody prepared. And then it didn't happen.

So this is not quite the same thing, but you know you have got sites where this is under study. You know that unfortunately lapses can occur. So do you have like a 35- or 50-mile radius around these sites where you are at least notifying the people on the front lines, the emergency rooms, the emergency room doctors, that this is something we are working on in your community.

Mr. {Sosin.} Thank you for that question. First with respect to hardening infrastructure, yes, there are support programs at the state and local level to address anthrax and other bioterrorism threats. As you pointed out, there are not only the routine treatments, there are some advanced medical countermeasures that have been developed such as antitoxin to help treat later stages of anthrax and vaccine.

Those were actually brought to bear, the vaccine and antibiotics and prophylaxis in this incident.

The state authorities are informed of the institutions and their jurisdiction and the agents that are there as a part of their public health preparedness programs. There is no active outreach to the medical community in the absence of an incident, but we are quick to respond as we did in this instant with the information about how to diagnose, how to watch for, monitor, and how to treat.

Mr. {Burgess.} Let me just interrupt you because my time is going to drift away from me. Could you provide the committee those materials that you provided--

Mr. {Sosin.} Absolutely.

Mr. {Burgess.} --to the emergency rooms and what radius around where the breach occurred, what the geographic radius was?

Mr. {Sosin.} I will say that these materials were not sent to emergency departments, although we did consider it. We were monitoring the workers in the laboratories closely, and these materials were sent to the laboratories and to the state health department.

Mr. {Burgess.} But Dr. Sosin, that is the point.

Mr. {Sosin.} Yeah.

Mr. {Burgess.} These people thought they were getting inactivated strains, and they were active. So somebody leaves work for a weekend and Sunday afternoon has got a low-grade temperature, just doesn't feel right. A family member says go down to the Care Now facility, and again, they will look well until they get deathly ill.

Mr. {Sosin.} Absolutely.

Mr. {Burgess.} That is the problem.

Mr. {Sosin.} That is why these were isolated to laboratories, and we were working directly with the laboratories, the workers, and the health departments to monitor them.

Mr. {Burgess.} Well, forgive me if I am unmollified, but the problem was you didn't know what you didn't know at that point. And certainly the people in the community who may have been the doctors and nurses and the caregivers who were seeing patients wouldn't have known that this was what they were up against.

I guess my concern is how do we get that information out

there? How do we make people aware? Once you know that anthrax is in the consideration, okay. Fair enough. But before you know it, they look like the last 1,500 patients that have come through the door with a viral syndrome.

I do have a question that I need to ask Mr. Demske, and if we don't have time to get through all of it, maybe you can provide me an answer in writing. But when you look at the referrals for violations of the Federal Select Agent Program, CDC, NIH, United States Army Medical Research Institute of Infectious Diseases seem to be the top three. So you have an enforcement policy where you can actually find, but you don't find federal agencies. Is that correct?

Mr. {Demske.} To date we have not fined any federal agencies. That's correct.

Mr. {Burgess.} But that seemed--you know, that is what Willie Sutton would say. You robbed banks because that is where the money is. Right now, the violations, the multiple violators seem to be coming from those three groups. So can you get back to me in writing and discuss what you are doing to consider providing the same civil money penalties at any other lab, any other lab in the country would have to face if

they had breech of these agents.

Mr. {Demske.} Just to be clear, most of the referrals and most of the labs, incidents that have been referred to us, have not involved federal entities but certainly there have been repeat instances at federal entities, and we would be happy to provide you an answer.

Mr. {Burgess.} The multiple offenders at CDC, NIH, and the United States Military. That is the problem.

Mr. {Murphy.} It is the civil penalties and other penalties we need to know about from there. Thank you.

Mr. Tonko, you are recognized for 5 minutes.

Mr. {Tonko.} Thank you, Mr. Chair. We have heard about the importance of keeping labs safe and secure. Thus I would like to explore how labs both private and public that fail to meet critical safety standards and regulations are held accountable. Both CDC and HHS, through their Offices of Inspector General have roles and enforcement. CDC's division of select agents and toxins can refer entities, the Office of Inspector, for civil money penalties or certainly notices of violation. CDC could deny, revoke, or suspend a lab's registration or require a lab to enter into a performance

improvement plan. Criminal charges can also be made in cases of misuse, unauthorized possession, or unauthorized transfer. So Dr. Sosin and Mr. Demske, could you briefly walk us through the different enforcement options and how you determine the appropriate response for a given violation?

Mr. {Sosin.} Thank you for your question. You have correctly pointed out options, the administrative options the CDC has to suspend, deny, or revoke registration. The registration process itself is intended to screen and assure that there is good laboratory practice, good laboratory leadership and an appropriate use for the select agent materials.

So that process and a variety of other steps in the program are intended to assure that the entity itself is taking the appropriate steps that it needs to take. The decision to suspend or revoke is one taken very seriously on the importance of balance, particularly for facility of the nature that you all are talking about here. These are important biodefense facilities doing important work, and the history of the program has been to work collaboratively with these programs to identify the specific problems and address

them. But those are options, and the referral to FBI if there is a concern about suspicious activity or referral to OIG.

Mr. {Tonko.} Thank you. Mr. Demske?

Mr. {Demske.} Yes. When we receive a referral from the CDC, one of our attorneys or multiple attorneys will review the allegations and the findings of the CDC, will often consult with the scientists and expert at CDC so that we make sure we understand those facts. If we believe that there has been a violation, it is our policy to them contact the entity that is the subject of the matter and give them the opportunity to provide us with information or arguments about why the penalty would not be appropriate. We take that into account, often again in consultation with CDC and decide whether to go forward with the case and we use our--looking across the experience of the cases that we have had, make a judgment about what we think the case should be valued at if we do seek a civil money penalty.

Mr. {Tonko.} Now, do your offices routinely work together to take action against those who are in violation?

Mr. {Demske.} We certainly communicate and work

together from our perspective to make sure that we understand the facts and the science in these matters for us to determine whether to go forward.

Mr. {Tonko.} And Dr. Sosin, what types of violations would result in a lab losing its registration?

Mr. {Sosin.} I can tell you that the process of revoking a registration is one that is undertaken through careful efforts to help the laboratory address the concerns and improve its practices and that revocation would come only after the inability of that facility to make those changes or their decision to no longer be interested in doing that work. I can get further clarification of the specific measures if you'd like.

Mr. {Tonko.} And in your opinion, how often has that happened?

Mr. {Sosin.} I believe that it has happened two times. I can get you the exact number.

Mr. {Tonko.} Okay. I would also like to get a sense of the frequency of violations and actions to address them. Dr. Sosin, are you seeing any trends at the CDC in terms of enforcement actions, any trends in referrals to the Office of

Inspector General for instance or performance improvement plans or lab registration actions?

Mr. {Sosin.} The Federal Select Agent Program is constantly evolving in its approaches and tools such as the corrective action plan process are relatively new and evolving. So trends are hard to evaluate in that context. I know that request of this subcommittee, specific enforcement actions have been laid out in a response and should have the kind of information you would be looking for.

Mr. {Tonko.} Okay, and I am out of time, but if Mr. Demske, if you could perhaps feed the panel with that same trend that you cite, any trends that you cite, that would be helpful.

Mr. {Demske.} Yes.

Mr. {Tonko.} Thank you.

Mr. {Murphy.} Thank you. I now recognize Mrs. Blackburn for 5 minutes.

Mrs. {Blackburn.} Thank you, Mr. Chairman, and thank you to our witnesses for your patience. We appreciate this. As you know, we have got another hearing going on this morning.

Dr. Sosin, I want to come to you if I may. I have got a copy of Dr. Frieden's testimony from this committee last year, and he was testifying about the June 2014 anthrax incident. He said, and I am going to read from the testimony, and I am quoting. ``These incidents should never have happened. The lack of adequate procedures and oversight that allowed them to happen was totally unacceptable. We will explore the broader implications of these incidents and incorporate the lessons learned from them to proactively prevent future incidents at laboratories across the Nation that work with pathogens.''

So I want to know, can you explain why we didn't seem to learn the lessons? Can you talk about why there is another comprehensive review of safety and security of the bioterror labs? Why was not Congress notified? Why is another review necessary? Were the problems at the CDC not corrected? And then who is going to conduct the new review? And ultimately, who do we hold responsible for this?

Mr. {Sosin.} Thank you for your questions. Pardon me if I need refreshing on some of them.

Mrs. {Blackburn.} I will be happy to refresh.

Mr. {Sosin.} I am sure you will. I think it is important to recognize that the oversight program is not a CDC laboratory itself. It functions separately. Nonetheless, in hindsight, there has been reason to look more closely at anthrax inactivation. There is no question that that is necessary, and before a moratorium on the use and transfer of these materials will be lifted, we will have a policy about how to validate--

Mrs. {Blackburn.} Whoa, whoa, whoa. Wait a minute. That was supposed to be done. So why was it not done? Who is responsible that it did not get tended to last year?

Mr. {Sosin.} The work of a complex laboratory, microbiological laboratory, has thousands of procedures and potential vulnerability.

Mrs. {Blackburn.} So you are saying no one person is in charge, that it is done by committee?

Mr. {Sosin.} No. I am saying that the nature, the current nature of the Federal Select Agent Program is one of setting broad standards to achieve high laboratory performance but does not review each individual specific procedure at each entity. There will need to be--

Mrs. {Blackburn.} Well, did the procedures call for notifying Congress?

Mr. {Sosin.} I am sorry?

Mrs. {Blackburn.} Did the procedures call for notifying Congress if you need to do a review, if you have another incident?

Mr. {Sosin.} So--

Mrs. {Blackburn.} So that is not a part of your best business processes?

Mr. {Sosin.} I apologize if Congress was not notified regarding the review that Dr. Frieden requested we take internally of the Federal Select Agent Program at CDC. That review is not a review of CDC labs and procedures. That is a review of what opportunities we have--

Mrs. {Blackburn.} Okay. Well, let me ask you this--

Mr. {Sosin.} --to improve the oversight program.

Mrs. {Blackburn.} --this way. Going back to his testimony where he says that it never should have happened, lack of adequate procedures, totally unacceptable, going to put the processes in place, and incorporate the lessons learned. Was this not done last year?

Mr. {Sosin.} Many things were done. This was not addressed.

Mrs. {Blackburn.} So, okay. So it was not addressed? That is the answer that I wanted a yes or no. Either it was done or it was not done, and that is what we want to know.

And see this is what is part of is so frustrating to the taxpayers who are footing the bill for this because you all feel like you have immunity if you will, and you don't have to move forward and do the job because you have a continuing appropriation. You just don't do the job until it is convenient.

Mr. {Sosin.} Congressman, I don't believe that--

Mrs. {Blackburn.} So you mess up once. You mess up twice. You mess up 86 times, and it is no skin off your back because nobody is responsible, because you operate by committee, because we ask you to do something and report back to us. What do you do, sit around and go, well, we will get around to it later? Maybe we need to give you around to it and have you go get the job done.

Mr. {Sosin.} Perhaps I am misunderstanding--

Mrs. {Blackburn.} The fact that we are having to have

another hearing and look at this is something that is frustrating. You should realize that there was a mistake and immediately move forward to correct the procedures and the policies and then should change the way that things are done. And I know I am running out of time, and I will yield back the balance of my time.

Mr. {Sosin.} I do think it is important to clarify that the CDC error with anthrax was addressed. It was a different situation. What I did acknowledge is that as the Federal Select Agent Program, with anthrax, with inactivation, in hindsight we should have and we will address inactivation procedures before that is used again.

Mr. {Murphy.} I am sure you can understand--

Mr. {Sosin.} Absolutely.

Mr. {Murphy.} --we have heard that before.

Mr. {Sosin.} I understand.

Mr. {Murphy.} Ms. Castor, you are recognized for 5 minutes.

Ms. {Castor.} Thank you, Mr. Chairman. Regarding the DoD review of the Dugway incident and the science surrounding inactivation protocols, the DoD review concluded that one of

the root causes of the Dugway incident was scientific uncertainty about the process of inactivating anthrax spores. The review stated that this uncertainty led to the creation of protocols that do not completely or permanently inactivate anthrax spores. And although this instant only recently raised questions about the inadequacy of these procedures, the Department knew of this uncertainty for quite a while.

So Dr. Hassell, if the Department was aware of the potential inadequacy of the inactivation process using gamma irradiation, why didn't the Department have better verification procedures to ensure the spores were properly inactivated before shipping them?

Mr. {Hassell.} So that is a good question because it really separates there were two issues involved. One was the inactivation was ineffective, and then the other one was that the viability testing didn't catch the fact that the first was not 100 percent effective.

Regarding the inactivation, there are several scientific publications and, you know, peer-reviewed journals in the scientific literature that have shown different what we call death curves for killing anthrax. What we need to do now is

to try to pull all those together, get a consensus view of those, work with a body of subject matter experts, work in consensus with CDC and try to figure out what--

Ms. {Castor.} Well, why didn't you do that before if the Department knew of this uncertainty for a while?

Mr. {Hassell.} It appears that that was somewhat localized, that it wasn't universally acknowledged.

Ms. {Castor.} What does that mean?

Mr. {Hassell.} Well, each individual laboratory set its own standards. And so this wasn't raised up to a central body--

Ms. {Castor.} And you are acknowledging now that was not acceptable. Those standards were not acceptable.

Mr. {Hassell.} Was not acceptable and going forward, it will have to be done in concert so the--

Ms. {Castor.} So is the DoD reviewing all of its protocols and procedures to ensure that there are not similar gaps in the scientific literature for the inactivation of other dangerous toxins and pathogens?

Mr. {Hassell.} We will be doing that, definitely. We are going to take a--

Ms. {Castor.} So you are doing that for anthrax and for other toxins?

Mr. {Hassell.} Right. We are going to see if there are any lessons learned from that that we can then apply across the board.

Ms. {Castor.} How confident are you that people are going to take that seriously? There are gaps in science. There are discrepancies. How will you come to reconcile? Certainly you would err on the side of safety?

Mr. {Hassell.} Yes, ma'am, absolutely.

Ms. {Castor.} But take us through what is going to happen specifically in that review.

Mr. {Hassell.} Well, anthrax is particularly hard to kill. So we are taking on the biggest challenge up front. So that should give us our biggest challenges, both in the activation and on this viability testing afterwards. Things that we learn from both of those we will then take forward and apply them.

Ms. {Castor.} And when there is a difference of opinion, who is going to be the responsible party where we can go back and say, wow. We had this hearing. The DoD

said, another agency said we will address these gaps. If and when we have to have another hearing, who is it that we will identify? Or if you could provide that to the committee because there is this problem with no personal accountability, don't you agree?

Mr. {Hassell.} Yes, ma'am, and the second part of this investigation we will be looking at the accountability. We will have some of those people identified, and we will certainly provide that to the committee.

Ms. {Castor.} Thank you. I would like to turn to Dr. Sosin to ask some questions about the CDC's role in overseeing the Select Agent Program. Dr. Sosin, why is there such variation across labs as to how they inactivate anthrax?

Mr. {Sosin.} Thank you for your question. As mentioned earlier, there are a variety of needs for materials that come from dead anthrax, and the laboratories, some research, some production for proficiency testing of labs, et cetera, have different roles and purposes as well. So CDC historically has required a validated procedure, either published and followed or validated within that laboratory and proof of sterility testing. I think to your earlier question about

accountability, the exemption of a select agent, anthrax becoming now exempt because it is dead, is a requirement of the Federal Select Agent Program. And until we have a procedure that increases confidence that we can safely do that--

Ms. {Castor.} Because--

Mr. {Sosin.} --we will not lift that moratorium.

Ms. {Castor.} Well, I appreciate that, but you can see that we are very concerned.

Mr. {Sosin.} Absolutely.

Ms. {Castor.} Are we to expect similar variations in inactivation protocols for other select agents and toxins? And how do we address that?

Mr. {Sosin.} As Dr. Hassell pointed out, the nature of a spore being extremely hearty and difficult to kill, plus the fact in this instance we were, or the Department of Defense was trying to kill the organisms without disrupting the organism creates a challenge in safety. The attempt now is to set an appropriately wide margin. If you go back to the chairman's figure that he showed, the DoD shows the dosing and a gap between the kill curve and the dosing. That

gap wasn't happening here. Clearly there were production runs that were growing anthrax and should have highlighted that the procedure was not adequate.

Going forward we will make sure that there is a safety margin and achieve consensus with the broad input that we have opportunity to get to assure that we are taking the right margin.

Ms. {Castor.} I am out of time. Thank you.

Mr. {Murphy.} Thank you. Now I recognize Mr. Griffith for 5 minutes.

Mr. {Griffith.} Thank you very much, Mr. Chairman. Dr. Hassell, if you could, we have got folks out there receiving this. You answered a previous question related to the foreign nations and said some of those were DoD facilities. Were they all DoD facilities? And if not DoD facilities, were all the facilities that were completely controlled by the United States Government? Yes or no.

Mr. {Hassell.} No.

Mr. {Griffith.} So some of these would have gone to facilities not controlled by the United States Government. How certain can we be that these folks who were receiving

live samples, and I believe it was over the course we now know of like 10 years, didn't discover this before they necessarily told us and have been out there growing some of their own samples and siphoning off some? So when we are told that you all hunted it down and you have killed or acquired all of the live anthrax, how certain of that can we be? Because it doesn't sound like to me we can be very certain if somebody was taking some of that anthrax and skimming off some of the live for use in other ways.

Mr. {Hassell.} So the non-DoD facilities that you refer to, those are some of our most trusted allies. We do many things with these allies across the board, not just for chembio--

Mr. {Griffith.} They are trusted, but if they wanted to do research on biological weapons, this would have given them an opportunity to acquire that or at least to acquire the base material to start the cultures with. Isn't that true? Yes or no.

Mr. {Hassell.} It is true, but they were already doing most of that work. They just--we were trying to use a common material across the board so everyone was testing on the same

material so that we could compare the results that we have.

Mr. {Griffith.} And how--

Mr. {Hassell.} But they do have those programs already.

Mr. {Griffith.} How comfortable are you with at those facilities had better protocols than we do in that we don't have some worker who might have taken what was supposed to be some dead cells, generated the live cells, and gone out with a sample that he might have then got, he or she may have then given to a foreign agent?

Mr. {Hassell.} In some of those cases, they already have the material now. Like I say this was soon-to-be dead material, and we do have records that that's all been destroyed.

Mr. {Griffith.} What you found has all been destroyed but since it was live, there could be more than what you knew about. Yes or no. Yes, the answer is yes. All right. Let's move on.

Dr. Sosin, you said that the CDC acted reasonably in tracking down the live anthrax and then securing or killing it. Dr. Crosse, you indicated that you would give them a B once it was discovered, but Mr. Demske, you didn't get

notified until yesterday to investigate the problem that was discovered in May. Isn't that correct?

Mr. {Demske.} That is correct, yes.

Mr. {Griffith.} So we have got at least 60 days since the problem was discovered before you were notified. Isn't that true?

Mr. {Demske.} Yes.

Mr. {Griffith.} I don't consider that a B or acting reasonably. Do you?

Mr. {Demske.} Well, we are not the front lines of an emergent situation. That would have to go to the FDA and with the scientists and the CDC. So it is normal or CDC to do investigative work on its own before it would refer a matter to us, and that actually helps us because the evidence is more developed when we receive it.

Mr. {Griffith.} So you think 60 days is reasonable before you're notified to do your investigation?

Mr. {Demske.} Yes.

Mr. {Griffith.} Okay. And as a part of that, they are doing their investigations and so forth. But don't you think it is kind of interesting that you got notified yesterday?

Do you think that our hearing might have sped that time up a little bit?

Mr. {Demske.} I have no information about that.

Mr. {Griffith.} But when you filed your testimony, you said to date OIG has not received a referral for any more recent potential violations involving Dugway which was in reference to the 2008 and 2010 incidents.

Mr. {Demske.} That is right. We submitted the testimony on Friday. At that time we had not received it. I would say--my opinion is that oversight by this committee is a very effective way at spurring attention to this matter within the government.

Mr. {Griffith.} I just wish we didn't have to do it so often. Dr. Sosin, you are the acting director of National Center for Injury Prevention and Control. I noticed in the report referred to by the chairman earlier that Stephen Moore is the Acting Director of his department. What is the relationship between your two areas and why is everybody over there acting and nobody is permanent?

Mr. {Sosin.} I am sorry. The information you have about my acting director role is old. I was previously for

nine months acting director there. I have been for nearly or over a decade actually the Deputy Director for the Office of Public Health Preparedness and Response. Dr. Monroe I think you are referring to is the Acting Associate Director for Laboratory Science and Safety, is an outstanding laboratory scientist who comes from the Center of Emerging Infections.

Mr. {Griffith.} And he is--

Mr. {Sosin.} And he is in an acting role because we are trying to hire a top-notch laboratory scientist to lead the Laboratory Safety and Science effort.

Mr. {Griffith.} And do you answer to him or do you just work with him?

Mr. {Sosin.} I work with him.

Mr. {Griffith.} I yield back. Thank you, Mr. Chairman.

Mr. {Murphy.} Mr. Pallone, you are now recognized for 5 minutes.

Mr. {Pallone.} Thank you. As the investigation into the Dugway incident continues, we are learning that more and more labs received these lives anthrax shipments in addition to the 86 labs to which DoD directly sent shipments. There had been additional 106 labs that received secondary

transfers. So we are now talking about nearly 200 labs. And as more labs are involved, the opportunities for error only increase.

So I do want to understand whether it is necessary to have so many different labs involved with dangerous biological agents. I know Ms. DeGette mentioned this in her opening statement. So Dr. Crosse, do you have an opinion on the number of labs that are working with anthrax?

Ms. {Crosse.} Well, I don't think we know the number of labs that are working with anthrax. I think that is one of the issues. Well, we have information of where the--are you talking about the--

Mr. {Sosin.} I just heard entities.

Ms. {Crosse.} Yes.

Mr. {Sosin.} Anthrax is a select agent.

Ms. {Crosse.} That is right. I am sorry. Anthrax we do know. We do not know all of the high containment laboratories that exist. We have controls for a subset of dangerous pathogens. There are other highly infectious pathogens that require a biosafety level three laboratory, and they do not all have to be registered with the Select

Agent Program. We do know for anthrax. My apologies.

Mr. {Pallone.} So Dr. Crosse, GAO has recommended the establishment of the single federal entity to conduct government-wide strategic planning and oversight for high-containment labs. This would include developing national standards for designing, constructing, operating, and maintaining such labs. Can you elaborate on this recommendation?

Ms. {Crosse.} Yes. We think it is important that there be a more comprehensive set of plans for how many labs are needed. You know, there have been a great increase in the number of labs over the last decade. Since the anthrax attacks in 2001, a number of different federal agencies have expanded the number of labs that they have. Academic institutions have built labs. Some states have built labs. And a lot of private entities have built labs. And they are very expensive. We don't know what really is needed.

As we have heard today, they are developing their own validation procedures. And there's not necessarily an assurance of consistency. And so while inspections can be performed at that these laboratories, the kinds of reportings

of problems have only typically been going to a level above the laboratory, too. So they are not going up to the top of department or to organizations.

And so I think that we are concerned that there hasn't been kind of a consistent set of standards in place, a consistent understanding of what the needs are, a consistent plan developed for where these laboratories ought to be built and maintained, and what the costs are going to be over the long term for maintaining this kind of infrastructure and whether it is in line with the needs.

Mr. {Pallone.} Well, have you gotten feedback from the Federal Government agencies that operate these high-containment labs with regard to this recommendation to establish a single federal entity? I know you mentioned some obstacles to that, but what other obstacles would there be to implement it?

Ms. {Crosse.} Well, you know, I think that it is not clear where that organization should be located. As we've heard today, it is difficult to retrofit this kind of control on top of an existing enterprise. Different departments want to have control over what their own needs are. Different

companies want to be able to compete for contracts from the Federal Government. And so going back and retrofitting them kind of control is complicated. We have not gotten traction on the concept of moving forward to try to centralize this control.

Mr. {Pallone.} Let me just then ask again, do you believe that the establishment of these national standards and oversight might address some of the gaps that led to the recent incidents at DoD and CDC? And how could Congress help in establishing uniform standards and procedures?

Ms. {Crosse.} We do believe that having more consistent lines of authority would be helpful. DoD I think in its report on the Dugway incidents has pointed out that the different laboratories handling anthrax were in different chains of command and never came together that there wasn't a sharing of information and they didn't have top-level knowledge of what was going on in these laboratories and how the procedures were being conducted. That is the type of thing we think would be helpful, and we would be happy with you and members of the committee to try to develop some kind of proposals.

Mr. {Pallone.} Thank you. Thank you, Mr. Chairman.

Mr. {Murphy.} Thank you. I now recognize Dr. Bucshon for 5 minutes.

Mr. {Bucshon.} Thank you, Mr. Chairman. I mean, to me this hearing is astounding, honestly. And I hate to admit but in the 4-1/2 years that I have been here, this is not the only government agencies that we are hearing, testifying in front of a Congress saying they are establishing new policies. Sorry we messed up. Sorry we did this. Sorry we did that. And you know why? Because there is no accountability. There is no accountability across the Federal Government in my view. No one is responsible. People are in there jobs for short periods of time. Dr. Hassell, you have been on your job for a year. If we really pressed you, you would say, well, I don't know. I have only been in my job for a year, so I don't know what they did before me. I mean, this is a decade-long process, and I personally get tired of hearing about how we are establishing new policies in this. This is anthrax. We should have had policies for decades. It is ridiculous.

And you know, that is the problem. There is almost

contempt against congressional oversight. Every hearing I go to--and it is almost people walk out of the room and they go, well, they didn't get us this time and they can't get us. There's nothing they can do to us. That is what--I mean, this is just ridiculous.

So Dr. Hassell, how can there not be standardize protocols for this in the Federal Government after decades and decades of this? How can that not happen? I mean, that is just the question I have. Dr. Hassell, how could--you made the statement. You know, we are standardizing how we deal with this. How can it not be standardized.

Mr. {Hassell.} I could answer for DoD. Part of it was as noted earlier that the different chains of command has been one of the fundamental problems here because each laboratory reports up to a different chain. They meet too high up in the organization. So yes, I have been in place for a year, but I take this very personally.

Mr. {Bucshon.} I am not criticizing you.

Mr. {Hassell.} Right. No, no--

Mr. {Bucshon.} I am just saying--

Mr. {Hassell.} No, no, but I am saying I take--

Mr. {Bucshon.} In fairness, you have only been there a year. You are right. You can't be accountable for what happened 10 years ago. I agree with you.

Mr. {Hassell.} But I own it now, so I take personal responsibility to work with other people in the department to make sure these things are standardized, and I will not recommend to the Undersecretary that we lift the moratorium until I am confident that we have the proper scientific basis for our operations and that we have received, we have achieved the right level of standardization--

Mr. {Bucshon.} I appreciate that. The reality is is that if people are losing their jobs, this would be standardized. And Dr. Sosin, I mean, you said--they asked, how do you solve this problem? You said, well, I don't know how we solve the problem essentially is what you said in your earlier testimony.

I mean, I know how to solve it. How many people across the government have been fired over this problem? Who has lost their job at CDC, at DoD? Or who is still doing the same thing, even though they literally sent a national security risk, anthrax, around the world? And as Mr.

Griffith found out, non-DoD properties. I don't care if they are allies. That doesn't matter.

And not to mention the fact how many people are protected from being fired because they are part of a Federal Government union that does not allow them to be held accountable.

Mr. {Sosin.} Congressman--

Mr. {Bucshon.} I want to know answers.

Mr. {Sosin.} I would love to have you come visit CDC and see how accountable the scientists and professional staff are at CDC. We take this incredibly seriously. There are--

Mr. {Bucshon.} I am not saying that you don't--

Mr. {Sosin.} There are regulations and rules--

Mr. {Bucshon.} --but who has lost their jobs? Who lost their job?

Mr. {Sosin.} There are regulations and rules around the use and transfer of anthrax, live anthrax. This particular incident was about an exempted material, which was not considered a select agent. And new actions will be taken to address it.

Mr. {Bucshon.} What, you are going to put in some more

policies? By action, what do you mean?

Mr. {Sosin.} For example--

Mr. {Bucshon.} Well, for me it means--what it means to me is the people responsible for doing this lose their job.

Mr. {Sosin.} For example, before a material can be considered killed, we need to have a validated procedure within the lab experience.

Mr. {Bucshon.} But how--to my question, how come you haven't had that?

Mr. {Sosin.} Hindsight--

Mr. {Bucshon.} This is for decades.

Mr. {Sosin.} --we should have had it. We have already--I have acknowledged that in hindsight, with this organism and the vulnerability here, we should have done this before.

Mr. {Bucshon.} I mean, the reality--

Mr. {Sosin.} And we are going to do it now.

Mr. {Bucshon.} I mean, the Federal Government hasn't known what constitutes dead anthrax until this came up? I mean, I just don't--

Mr. {Sosin.} The reliance is--

Mr. {Bucshon.} Failing to find why there is a problem--

Mr. {Sosin.} --testing, testing the material in the laboratory to see if there is growth. And that process in this instance failed.

Mr. {Bucshon.} Okay. I yield back, Mr. Chairman.

Mr. {Murphy.} Thank you. I now recognize Mr. Flores for 5 minutes.

Mr. {Flores.} Okay. Thank you, Mr. Chairman. It is unfortunate that we have to have another hearing, another oversight hearing like this. You know, continuing along the theme that Dr. Bucshon raised, there was a quote in USA Today in the article that came out yesterday that says the root cause of all this is a lack of accountability. Incidents don't get reported, and consequences don't occur. And I think many of us have expressed our frustration, not only in the agencies represented here, the two agencies that are the subject of the problems, but across the government and the VA for instance. It has allowed for cover-ups on waiting lists, and only three people have been fired at the VA. Three hundred thousand people in the VA and only three have been fired. And it gets back to one of the root causes: It is too hard to fire a federal union employee.

So Dr. Hassell, of the individuals at the Dugway Proving Ground, what are the percentage of uniformed versus civilian at that facility?

Mr. {Hassell.} I don't have that information, sir. I can get it to you. It is mostly civilian.

Mr. {Flores.} And of the civilian, what percentage are unionized?

Mr. {Hassell.} I am not sure.

Mr. {Flores.} I would appreciate if you could get us responses from both of those.

Mr. {Hassell.} Yes.

Mr. {Flores.} And if that is the case, have you taken action against any of those employees, any civilian employer or any uniformed employee?

Mr. {Hassell.} To date, no.

Mr. {Flores.} Okay.

Mr. {Hassell.} There is an investigation that's starting to look into this. If we do take action, we want to make sure that it is taken at the right place, to make sure that the person who is truly accountable is held accountable.

Mr. {Flores.} Well, that is all real nice, but how many

mistakes are happening right now because there is no accountability? I mean, do you know today that we are not shipping other live agents around right now? Do you know that? How can you know?

Mr. {Hassell.} As we pointed out, just because the anthrax itself is so hard to kill and presents such a challenge, that has been stopped. So that I can assure you is not happening.

Mr. {Flores.} Okay. Anything else? What is the next one, though? Where are the other vulnerabilities? I mean, we had Ebola last year, not from you but from the CDC. I mean, Dr. Sosin, how can you be sure that we don't have any other incidents like this going out right today.

Mr. {Sosin.} Certainty is hard to provide. As we understand the organism and the process of assuring its sterility. There is no evidence that these materials that are presumed inactivated are not inactivated. We have seen no evidence of a signal event, growth or disease or injury. That doesn't mean we don't take this seriously, and we don't consider whether additional procedures need to be implemented on inactivation of select agents. This is certainly going on

now with respect to anthrax and we'll apply what we would consider in a broader context for other selected agents.

Mr. {Flores.} Just for the committee's sake, walk through the ownership of the different elements of the Federal Select Agent process as respects your two agencies. Can you tell me who owns what part? And I have just got a minute so can you--just give me the highlights, Dr. Sosin.

Mr. {Sosin.} Well, I can tell you--

Mr. {Murphy.} What parts do you own and then where do you hand off to?

Mr. {Sosin.} The Federal Select Agent Program is an oversight program so the main activities that are involved and the main improvements that have been made through the execution of this program over the last 12 years includes screening and assessing facilities and staff for their suitability to work with anthrax. That means that the facility is an appropriate facility, has good laboratory practice and has appropriate rule to work with that material. If also includes the FBI's review of personnel reliability, of all of those who will be using it, includes a set of requirements to elevate biosafety and biosecurity, inventory

management, access controls, those kinds of measures. And it includes a process and an ability to detect and respond including the notification of jurisdictions that have these facilities in site including what we did here with the anthrax response, being able to go in, investigate, identify whether people are at risk, secure the samples and look into what caused them.

Mr. {Murphy.} Okay. Now this process involves not only private-sector institutions as well as public-sector institutions, is that correct?

Mr. {Sosin.} That is correct, for the select agents.

Mr. {Murphy.} So where are you finding the best practices coming from today? I mean, Dr. Hassell was talking about going to the private sector to find best practices. So Dr. Hassell, where are we finding the best practices today? Private sector or public sector?

Mr. {Hassell.} It is a combination of both. I am just saying we are going to go look at the private sector. That often doesn't happen in government as the first reaction. The Department of Defense--

Mr. {Flores.} You need to look at both.

Mr. {Hassell.} The Department of Defense, the Centers for Disease Control, the NIH, these are outstanding facilities. They are doing cutting-edge, critical work which has some risk. These are places where best practices and not best practices will occur because of the broad range of practices that do occur.

Mr. {Flores.} Okay. I have additional questions. I will submit them for the record later on. Thank you, Mr. Chairman.

Mr. {Murphy.} Thank you. And the gentleman from Oklahoma, Mr. Mullin, is recognized for 5 minutes.

Mr. {Mullin.} Thank you, Mr. Chairman. I appreciate you guys being here. I am sure you are having a blast and enjoying your time here, but it is very frustrating for me to see what has taken place and to hear you guys say you have protocols, protocols. You are looking into it. You are looking into it. How long does it take to look into this? It is really hard for me to follow this. Dr. Hassell, is it the practice of the DoD, the labs, to send out a death certificate with select agents when they leave, is that correct?

Mr. {Hassell.} It has been, yes.

Mr. {Mullin.} It has been? How long has that been going on?

Mr. {Hassell.} I believe--I apologize. I am not sure when the death--I think the information--

Mr. {Mullin.} What kind of information is on that death certificate, the one that is similar to this one right here?

Mr. {Hassell.} I am not sure how long that has been part of the process. We have been looking at just the overall activation. We have been looking at that back 12 years. I am not sure at what point the death certificate was initiated. I can--I will find out.

Mr. {Mullin.} Well, this dates back to 5 years ago. So we know it has been going on for at least 5 years, right?

Mr. {Hassell.} Right.

Mr. {Mullin.} Then why is it that the private lab that found the active anthrax, why didn't it have a death certificate with it?

Mr. {Hassell.} Because when it was originally tested they didn't see growth. One of the things we are looking into--

Mr. {Mullin.} But if it shipped out--you just said it is the practice of DoD with any shipment that is leaving to have a death certificate. Why wasn't there one that was shipped to a private lab?

Mr. {Hassell.} Oh, I am sorry. So for that particular operation, we were setting out blind tests. People were seeing whether or not--

Mr. {Mullin.} With active anthrax in it?

Mr. {Hassell.} It was a suit to see if people could detect the presence of these. This was to identify some new performers.

Mr. {Mullin.} So we knowingly shipped live anthrax.

Mr. {Hassell.} I am sorry, say again?

Mr. {Mullin.} Well, you said you were shipping it to him to see if they could find it. It didn't have a death certificate, so I am assuming you knowingly shipped live anthrax to this private lab because it didn't have a death certificate. I forget what that--

Mr. {Hassell.} No, it just--we did not provide the shipping because of what the agent was? We did not knowingly ship live agent, absolutely not.

Mr. {Mullin.} Did the shipment then have--

Mr. {Hassell.} We just did not include their--

Mr. {Mullin.} --at your place or some other place a death certificate?

Mr. {Hassell.} Yes.

Mr. {Mullin.} Who produced a death certificate?

Mr. {Hassell.} The originator at Dugway.

Mr. {Mullin.} And what was the test that was performed to show that it was dead? And what is the difference between the tests that the private lab showed that it was live?

Mr. {Hassell.} They were very similar and--

Mr. {Mullin.} Well, they couldn't have because one showed it dead, one showed it live.

Mr. {Hassell.} Well, that is what we are looking at because one of the key differentiators for what Dugway did--

Mr. {Mullin.} So who is responsible for that? Is that Dr. Sosin? Is that his group? Who is responsible for showing the procedures to find out that it is dead?

Mr. {Hassell.} Going forward we are going to adopt the CDC's procedure.

Mr. {Mullin.} No, no, no. Who is responsible for it at

that time, not going forward? Who is responsible for it at the time? If it wasn't your group, Dr. Hassell--

Mr. {Hassell.} It was Dugway.

Mr. {Mullin.} --whose group was it?

Mr. {Hassell.} It was Dugway. They developed--

Mr. {Mullin.} And who is over Dugway?

Mr. {Hassell.} --the testing.

Mr. {Mullin.} Who do they fall underneath? Do they fall underneath Dr. Hassell, Dr. Sosin, Dr. Demske? Who do they--who oversees Dugway?

Mr. {Hassell.} The Army.

Mr. {Mullin.} Okay.

Mr. {Hassell.} That is why--

Mr. {Mullin.} Narrow it down for me here. Help me figure out who is responsible. Who is the chain of command that is responsible for the death certificate for the procedures to show that the agent's leading is truly dead?

Mr. {Hassell.} Are you talking about the chain of command at the laboratory or just for the certificate?

Mr. {Mullin.} I am talking about the chain of command to find out that the anthrax is shipping out. This isn't a

hard question. Who is over finding out for sure the procedures to find that the agent is dead?

Mr. {Hassell.} It would be the--

Mr. {Mullin.} You don't know?

Mr. {Hassell.} It would be the scientist that--

Mr. {Mullin.} You don't know. Dr. Sosin, can you answer that question?

Mr. {Sosin.} I can't answer--

Mr. {Mullin.} Dr. Demske, can you answer that that question?

Mr. {Demske.} Not specifically. I--

Mr. {Mullin.} Okay. Then this brings in my last question because as I was going through the background information to prepare for this hearing, I couldn't figure it out either. There are so many different people that touched this. There is no clear line of chain of command. As a business owner, you have got to have someone responsible for something. This goes back to a line of questions that was already asked. No one can be fired because no one takes responsibility for it because no one has responsibility for it. We just assume that everybody is doing their job, and

yet we are shipping out live anthrax and no one takes responsibility for it.

Dr. Hassell, you said that you were going to leave it locked down where they couldn't be shipped, for nothing to be shipped until you declared a line of command and procedures, right? How long is that going to take?

Mr. {Hassell.} It is going to take a minimum of 6 months we believe.

Mr. {Mullin.} A minimum? If you could just find out all the players in it, you ought to be able to lay it out and put somebody in charge to oversee it.

Mr. {Hassell.} I am sorry. I was referring more just to put the procedures--the scientific studies that need to identify the gaps but the--

Mr. {Mullin.} My point that I am getting to is we had live anthrax shipped out. No one takes responsibility for it. When I asked question to find out who is responsible for it, no one can answer it. I think we have identified the problem. It is time for someone to take responsibility. Thank you, Mr. Chairman. I yield back.

Mr. {Murphy.} Thank you, and we have Collins from New

York for 5 minutes.

Mr. {Collins.} Thank you, Mr. Chairman, and maybe I should maybe help us all step back a second. Clearly a bacteria-grown agent such as anthrax or C. diff with spores, completely different than a virus, right? Easy to kill a virus. So part of the concern I have heard as one of the last questioners is we know there is a lot of biological agents, a lot of potential weapon issues going on. And I think the concern of the committee is if we have this with anthrax, might we have it with something else like SARS, like smallpox, like whatever. But that is where maybe--not to give you suggestions in your testimony. You might want to help the committee differentiate bacteria from virus, just to give them the confidence level. There is a different ball game going on.

Now you use radiation because you are trying to penetrate the spore, correct? For your--you want to penetrate the spore, which is very hard. So the way that you prove it is dead, the death certificate, is you take a sample and put it in culture and try to grow it. Correct? You tell me--and you really didn't make that real clear here. I am

guessing the problem is they put it in culture for a month, and it should have been in culture for 6 months. Is it safe to assume that they just didn't run the culture test long enough?

Mr. {Sosin.} We can't identify for certain whether that was an issue, but it is a possibility. Anthrax grows in culture within 2 days generally. So it is--

Mr. {Collins.} No, your--it can but it can last 6 months. And this is where you take something like anthrax or C. diff which is a spore, it can pop up in 5 months' time.

Mr. {Sosin.} It can survive as a spore, yes.

Mr. {Collins.} That is correct. So if it is surviving as a spore for 5 months and somebody is creating a death certificate after 2 months, they are saying it is dead--

Mr. {Sosin.} I am sorry, Congressman. When you put a spore in a fertile environment, it germinates and grows--

Mr. {Collins.} Right.

Mr. {Sosin.} --and that, with anthrax, happens within 45 hours, generally within 24 hours. So in a fertile environment, you would expect to see that growth.

Mr. {Collins.} I can beg to differ with you. I have

some experience in this. I have seen it where it doesn't grow in a month. It doesn't grow in 2 months. And then all of a sudden in 5 months, it shows up. I would suggest respectfully that I believe the big issue here was it wasn't radiated with enough intensity, so it wasn't killed. But to validate it was dead, they put it in culture to see if it would grow. And if it was culture for 48 hours and it didn't grow and they gave it a death certificate, then I can tell you what your problem is right now. You didn't put it in the culture long enough. I think in best practices in industry, in industry best practices, you are going to see that batch sit in the refrigerator or sit in the freezer for 6 months, and you are going to have that culture, that spore in culture for 6 months, not for 48 hours. And I think you would have to agree, if it is in that culture for 6 months, it is deader than a doornail and you will have more assurance than if it is only in culture for 48 hours. And again, this is different than a virus. So I just think some of that confusion is going on here as to when is--because you do the death certificate at the lab after it has been radiated and held in isolation until the culture test is run. And then

you say okay, I didn't see anything. So it is dead. Now that entire batch is good to go as dead virus, hence exempted, et cetera, et cetera. And that is what happened. It was then shipped out exempt because it had the death certificate.

But I guess the issue would be--I am assuming that is up to the lab to decide how long they are going to grow it in culture, is that correct? That is a lab procedure, not a CDC or--

Mr. {Sosin.} At this point in time, the sterility testing, viability testing is a laboratory procedure, but there will be additional requirements as a result of this incident.

Mr. {Collins.} And I do think--and that is what I would encourage you to do. That is why I think it falls apart. You do trust these labs to all be at the top of their game. But in best practices, and this one an example, I can assure you best practice in private industry on anthrax and on C. diff is 6 months. It is 6 months of testing so you know it is dead. It is not 48 hours. That is best practice coming out of private industry. I yield back. Thank you.

Mr. {Murphy.} Thank you. And we now recognize the congresswoman from Indiana, Mrs. Brooks, for 5 minutes.

Mrs. {Brooks.} Thank you, Mr. Chairman, and thank you for holding this important hearing. And I have to say in my prior role before joining the committee, I was chair on the Subcommittee on Emergency Preparedness, Response, and Communications for Homeland Security, and it really opened my eyes to the vital need to better protect the American people and our country from bio attacks and from biodefense incidents. And I will say that at that time I learned that this administration did away with a position that had been in place under the Clinton administration, under the Bush administration, called the Special Assistant to the President for Biodefense. And I think we learned about that position being eliminated when the Ebola attack, when Ebola hit this country, and I think it kind of goes to the point of I think what Dr. Crosse is talking about is that as a government, we are not--there is no central line of authority. There is no central entity. There is no person who all of these issues bubble up to that as a government we have a massive enterprise with so many different well-intentioned,

hardworking scientists and government works. But yet, there is--when it comes to biodefense for this country, it is not organized and we are not doing a good enough job.

I have to tell you that later this week we are going to be introducing legislation that addresses the need to strengthen and streamline the existing biodefense initiatives BARDA and the CDC. And so Dr. Sosin, I have a question. If lab workers or other medical professionals had been exposed to live anthrax samples, are you confident as to whether or not we would have had proper vaccines and therapeutics in place to save lives?

Mr. {Sosin.} Yes, I am confident we do.

Mrs. {Brooks.} Are you confident, Dr. Hassell?

Mr. {Hassell.} Yes, ma'am.

Mrs. {Brooks.} Okay. Mr. Demske and Dr. Cross, are you confident that we have enough proper vaccines and therapeutics in place to save lives?

Mr. {Demske.} I don't have sufficient information to answer that question.

Ms. {Crosse.} Nor do I.

Mrs. {Brooks.} Dr. Sosin, would that be for the workers

that are being exposed or how about with respect to the community, building on Congressman Burgess' question about one of these individuals, if they had been exposed and presented to an ER. Can you, you know, explain to me what your view is if you have one about our national strategic stockpile and the coordination within the government enterprise with respect to the national stockpile.

Mr. {Sosin.} Thank you for that question. The strategic national stockpile actually did provide vaccine for the states that had workers who were receiving prophylaxis. So I am confident that we have the ability to do it. We have a vast supply of countermeasures for anthrax. The nature of the event that you might be trying to prepare for always determines whether you have enough. But there have been a variety of processes and procedures to review the requirements that have been set by the Federal Government by this threat, and we meet those current requirements.

Mrs. {Brooks.} Dr. Hassell, any comments on our stockpile and how we can ensure that we have the medical countermeasures in place across the board for incidents?

Mr. {Hassell.} No, ma'am. That is really my

colleagues' purview.

Mrs. {Brooks.} Dr. Cross and Mr. Demske, what I think this event, going back to what this event shows us, is that while we are trying to respond at a managerial level. Are you familiar with the private sector's involvement with the medical countermeasures, development, and procurement? Are either of you involved in that at all.

Ms. {Crosse.} I have done some past work looking at, for example, how the Federal Government has built flexible manufacturing facilities to be able to respond, and those are private sector entities. Mr. Demske?

Mr. {Demske.} I am sorry. I have nothing to add.

Mrs. {Brooks.} Okay. I would like to go back to, and I guess if I could actually--I might have a little bit of time with respect to the death certificate.

Building on the congressman's question about the death certificate, could both of you please explain with a little bit more detail how that process works, what is required to be placed on the death certificate, and if you are sending these spores to another lab, what is it that the one lab should have that the other lab then--what is common in

looking at the death certificate. Is the organism required to be listed or it is not listed when you do this sample blind test? Can you please go into a bit more detail? I am sorry my time is up, but I would ask if we might have just a couple of more minutes?

Mr. {Murphy.} One more.

Mrs. {Brooks.} One more minute?

Mr. {Murphy.} You will have to yield.

Mrs. {Brooks.} And then if you could please submit any further explanation in writing?

Mr. {Hassell.} So it might be, if I may, we can submit a more fuller explanation of how that is used. I will say though, we are considering not using a death certificate in our current operation. At least we are reevaluating that because it may send the wrong message. So that is one thing when I worked more with my colleagues about that very issue because we have concerns about what message that sends.

Mrs. {Brooks.} Dr. Sosin?

Mr. {Sosin.} The laboratory itself makes the determination about death certificates and the sending process. That is not a select agent regulation or

requirement.

Mrs. {Brooks.} Okay. Thank you. I yield back.

Mr. {Murphy.} Thank you.

Ms. {DeGette.} Chairman, I would like to strike the last word.

Mr. {Murphy.} We have one more--

Ms. {DeGette.} Oh, okay.

Mr. {Murphy.} We have one more on this. The chair now recognizes the congressman from North Carolina, Mr. Hudson.

Ms. {DeGette.} Sorry.

Mr. {Hudson.} Thank you, Mr. Chairman, and thanks to the panel for bearing with us here until the end. Would you like to expand on that answer at all, my colleagues question about the death certificates and the practice? Were you able to fully answer that?

Mr. {Sosin.} For myself, I need to get some more detail on that and give a better answer to that for all three of you that were interested in that issue.

Mr. {Hudson.} Okay. I offer you some time if you got anything else you want to say.

Mr. {Sosin.} No. I know that CDC does issue a death

certificate with materials, inactivated materials that it sends out on the occasions when it needs to. I do not know the particular details of that death certificate.

Mr. {Hudson.} Well, I would appreciate it if you all would follow up with that because my understanding is DoD in particular, it is common practice to send the death certificate, even when you are doing this sort of blind sample. And in this case, it wasn't sent until much later. So I would love to see a little more thorough answer on that. So thank you for that.

Overall, if anyone on the panel wants to, I am trying to grasp the mission of the Federal Select Agent Program, your understanding of the mission of the program, and do you think it is being fulfilled? I would open that up to anybody.

Mr. {Sosin.} Well, clearly the incidents that you have seen are serious, are the kinds of indicators that we need to do more, and I think the important message from us is that over the history of this program, since the regulations, the authorization in 2002 and the new regs in 2003, this program has continued to receive input and advice from a broad spectrum which is needed, advice from Congress, advice from

the public, advice from federal and non-federal entities to improve the program. And the program has changed and improved over time.

That said, this incident and these incidents have elevated the importance of some procedures requiring more direct oversight and review, and we will address that.

So there is a broad question, and many of those questions about BSL-3 that are not select agent, questions about how many labs. These are important, critical policy questions. Congress has an important role to play in them. The federal interagency has an important role to play in them. CDC will contribute to the debate about the pros and cons of the different approaches. But when consensus is achieved or direction is given, we will follow those directions.

Mr. {Hudson.} So in your opinion, the mission is worthy and salvageable I guess to try and use laymen's terms?

Mr. {Sosin.} Absolutely.

Mr. {Hudson.} Okay.

Mr. {Sosin.} We are committed to this work.

Mr. {Hudson.} Dr. Hassell, you know, the Dugway has had

problems in the past, continues to have problems, you know. It has been referenced plenty of times here today. Just in summation, how does this continue to keep happening and how do you see us getting out of this cycle?

Mr. {Hassell.} So I mentioned earlier that this falls under the Army. So speaking on their behalf, I can tell you that the Army takes this very seriously, at the highest level. Now that is something that sounds easy to say, but I can assure you, in my interactions with them, this is taken very personally and very seriously at the highest level. So the Secretary of the Army on down is taking action on this. They are going to look at issues specific to Dugway but not limiting it to that, looking at the chain of command across the board. And it is not just so that this could be a better reporting chain up. There may be opportunities that arise from this for better interaction across from them. The laboratory at USAMRIID for example may have some capabilities. Perhaps the organizational structure was preventing them, their free flow of information. I am not sure that is the case, but I am hoping that is some of the outfall from this. But you know, just getting all the

laboratories working better together, standardizing where it is appropriate, and then moving forward.

Mr. {Hudson.} Well, I appreciate that. I guess I would offer this up to the GAO or the OIG. What existing tools does CDC have that it is currently not using that would allow it to better oversee and take corrective actions against labs that commit violations? Either one of you.

Ms. {Crosse.} Well, we have a concern that the reporting when incidents occur is really just to one level up from the laboratory and that more senior management in an organization is not necessarily informed, that the Select Agent Program is really focused, you know, within that laboratory but not necessarily ensuring that accountability up the chain of command over that laboratory is occurring. You know, we also are just undertaking work at the request of this committee to look at inactivation procedures and the extent to which there are scientific questions for how that should be done, where there are best practices, what types of methods are being used, how that information is shared, you know, what the current scientific issues are, and how the methods are validated and whether that information is being

shared across this enterprise. And that is a concern that clearly labs have been operating on their own, and the information has not been being shared across the enterprise.

Mr. {Hudson.} I appreciate that. Mr. Chairman, I am out of time. If you wouldn't mind maybe answering in writing if you have just a summary of some of the tools, I would appreciate your testimony as well. Thank you, Mr. Chairman. I yield back.

Mr. {Murphy.} Thank you. And before we conclude, I think Ranking Member DeGette, you had a question?

Ms. {DeGette.} Yeah, thank you, Mr. Chairman. I just wanted to thank the witnesses for coming and also relay a conversation I had with Chairman Murphy which is I am really urging him to have a hearing later this fall, towards the end of the year, after you all have figured out what your improvements in the standardization and the oversight are going to be. What I have found during my many years on this committee is when we have some crisis like this, the witnesses come in. They say we need to do better. OIG and GAO come in and say there are things that can be done, and then another year goes by and we have another breech. So I

have urged the chairman and I think he is in agreement to really hold your feet to the fire to make sure that these improvements, these gaps that you have identified are filled, that the standards and the coordination, the plans are completed. And I believe he will have that hearing, and on both sides of the aisle, we would agree that needs to be done. Thank you very much.

Mr. {Murphy.} And I would also ask hopefully, when we talk to them, that we also have some accountability. You have heard several of the questions have been about how many people are going to lose their job over every fail over the last 10 years on this. So I think that is something that we are going to be looking for is to see how many people have lost their job as a result of this unaccountability.

So with that, in conclusion, I would like to thank all the witnesses and the members that participated in today's hearing. I remind members that they have 10 business days to submit questions for the record, and I ask that all witnesses all agree to respond promptly to those questions. And with that, the subcommittee is adjourned.

[Whereupon, at 12:09 p.m., the Subcommittee was

adjourned.]